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(54) Apparatus for mechanical transmyocardial revascularization of the heart

(57) An apparatus for creating revascularization channels in tissue, such as the myocardium of the heart, mechanically cuts the channels using a hand piece with easily removable cutting tip assemblies having angled, sharpened edges to allow rapid tip replacement. The cutting tip assembly has an inner needle within an outer hollow needle with each needle attached to the hand piece for independent rotation and axial movement. The

inner needle may be hollow, or formed with a pointed tip, and may rotate counter to the outer needle to enhance gripping and storage of the tissue excised by the outer needle. The hand piece may attach a cylindrical magazine of cutting tip assemblies or one cutting tip assembly. The cutting tip assembly may be heated to provide thermal damage to the heart muscle during the creation of the channel, providing some of the advantages of the laser method of TMR.

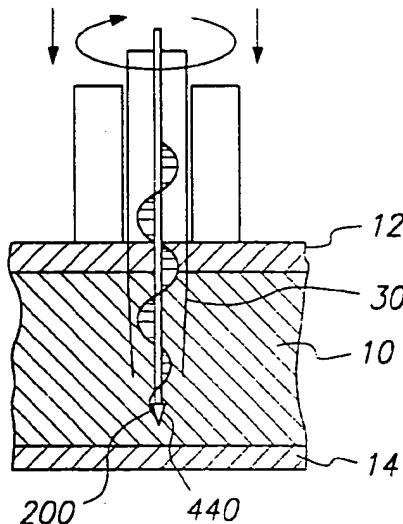


FIG. 3A

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Description

This invention relates to the field of surgical interventions for correction of coronary disease, and more particularly to the methods and devices for transmyocardial revascularization of the heart.

Heart disease is a significant health problem which has been the subject of substantial medical study. Bypass surgery has become commonplace; yet such surgery may be unavailable to many patients, either because of the nature of the occlusions or the physical condition of the patient.

One promising alternative technique for treating such cases is known as trans-myocardial revascularization (TMR). Although this technique was considered as early as the work of Dr. C. Beck "the Development of a New Blood Supply to the Heart By Operation", Annals of Surgery, Vol. 102, No. 5 (11/35), pp. 801-813, the method was not extensively studied until the work of Dr. M. Mirhoseini and M. Cayton, an example of which is found in "Lasers in Cardiothoracic Surgery in Lasers in General Surgery (Williams and Williams; 1989) pp. 216-223.

An early device to perform TMR is described in Aita et al., U.S. Patent No. 5,380,316, issued January 10, 1995. In the procedure described in that patent, a number of channels are formed through the myocardium between the ventricle and the exterior of the heart through the epicardium and myocardium by means of a laser apparatus. These channels were approximately 1.5 mm - 2.0 mm in diameter and approximately 1 to 3 cm deep. Clinical tests have demonstrated that such channels facilitate revascularization of the heart muscle and recovery of heart function.

Unfortunately, this technique has some attendant difficulties. The laser equipment for performing such procedures is large and expensive and may be unavailable to smaller and more remote medical facilities. Some patients may therefore find it difficult to gain access to a properly equipped medical facility when treatment is needed.

One alternative to the use of lasers would be to use a mechanical cutter to produce the channels.

Unfortunately, as noted in the Aita et al. patent, prior art methods of mechanical piercing and cutting of the heart wall produce tearing of the tissue. Such tearing leads to fibrosis, which combined with the problems of maintaining clear, clean channels, seriously diminishes the effectiveness of the TMR treatment produced by such methods. Hence, such prior art mechanical piercing does not adequately facilitate rapid and clean healing of channels.

Another alternative approach, melting of the myocardium by hot probes, has proven unsatisfactory, partly because there is no mechanism for removal of melted material from the channel.

It would therefore be desirable to produce clear, clean channels using relatively inexpensive and easily

transportable systems, which may be deployed in remote locations.

Broadly, an object of the present invention is to provide an apparatus and method for producing viable 5 channels suitable for TMR without the use of lasers being necessary.

More specifically, it is an object of the present invention to provide an apparatus and method for mechanically performing TMR without excessive tearing or 10 other complications which may cause blockage of the created channels.

It is a further object of the present invention to provide an apparatus and method for mechanically performing TMR without a requirement for large, expensive 15 equipment.

Embodiments of an apparatus of the present invention provide a hollow cutting device, which may or may not be heated, for mechanically cutting and removing myocardial tissue to create channels in the myocardium.

Still one more object of the present invention is to provide a hand held tool for deploying cutting devices for non-laser TMR procedures.

The present invention comprises a method and apparatus for mechanically performing transmyocardial 25 revascularization (TMR). Although the invention may be implemented in a variety of embodiments, several of which are illustrated herein, all require an apparatus with a special cutting tip assembly, preferably an easily removable cutting tip assembly which would allow rapid

30 replacement to permit several channels to be created in a relatively short period of time. This cutting tip assembly preferably has means for supporting the assembly in location on the heart wall while in operation. In several of the embodiments shown herein, the support means may include suction to assist in clean, complete removal of the material excised from the heart wall by the cutting tip assembly during formation of channels. In all embodiments there also is a mechanical means present to remove that material which is to be excised to form the

35 channel. Preferably, the cutting tip assembly is removably mounted to a hand piece with an actuator to deploy, rotate, and remove the cutting tip assembly. The hand tool may accommodate one or more cutting tip assemblies.

40 The cutting tip assembly optionally may be heated to provide thermal damage to the heart muscle during the creation of the channel, providing some of the advantage of the laser method of TMR. Such heating may be provided by placing the cutting tip assembly in a specially designed heater base which permits rapid connection of the assembly to the remainder of the apparatus while the cutting tip assembly is still in the heater. In this way the cutting tip assembly may be maintained at optimal temperature until the apparatus is ready to be deployed.

45 Some embodiments of the apparatus of the invention may be employed in a method for creating channels in the wall of the cardiac muscle appropriate for trans-

myocardial revascularization, the method comprising:

- rotating an inner needle disposed within a bore of an outer needle about the inner needle's lateral axis;
- orienting the lateral axis of the inner needle to insert with the surface of the external heart wall;
- translating the inner needle laterally along said lateral axis until the inner needle cuts partway into the heart wall;
- stabilizing the inner needle in the partial cut heart wall by ceasing rotation thereof;
- rotating the outer needle about its lateral axis, the outer needle being disposed such that the lateral axis of the inner needle and the lateral axis of the outer needle are substantially coincident, the disposition of the inner needle within the bore of the outer needle allowing relative lateral translation between the inner needle and the outer needle;
- translating the outer needle laterally along the lateral axis of the outer needle until the outer needle cuts the desired depth of channel into the heart wall and the excised tissue is held by the inner needle; and
- laterally withdrawing the inner needle and the outer needle.

Preferably, the method further comprises the step of heating the inner and outer needles to a temperature of at least 60 degrees Celsius.

In preferred embodiments, the apparatus may facilitate the step of applying a suction counter force while rotating and advancing the outer needle.

In further preferred embodiments the apparatus may be employed in a method comprising the step of rotating the inner needle while rotating the outer needle, the inner needle being rotated in a direction counter to a direction of rotation of the outer needle.

These and other objects, advantages and features of the present invention will be apparent to those skilled in the art from the following detailed description of preferred embodiments and the accompanying drawings, of which:

Figures 1A - 1E illustrate a presently preferred method and apparatus according to the present invention, utilizing a cutting tip assembly comprising two concentric rotatable needles.

Figures 2A - 2D illustrate a second preferred method and apparatus according to the present invention, utilizing a cutting tip assembly comprising a single hollow needle within a support means.

Figures 3A - 3C illustrate additional aspects of inner needles of cutting tip assemblies comprising two needles. Fig. 3A illustrates a drill style inner needle; Fig. 3B illustrates a screw style inner needle; and Fig. 3C illustrates an inner needle defining a side cut and a piercing tip.

Figure 4 is a perspective view of a mechanism for

mounting a cutting tip assembly of the present invention to a hand piece for rotation and axial movement.

Figure 5 is a side view of a preferred hand piece having a cylindrical magazine, shown linearly for purposes of illustration only, holding multiple cutting tip assemblies.

Figure 6 is a side view of another aspect of a hand piece for performing mechanical TMR and having a single, detachable cutting tip assembly.

Figure 7 is a front view of a heating block for cutting tip assemblies.

While a variety of embodiments of the present invention are disclosed herein, one exemplary presently preferred embodiment is illustrated in Figures 1A through 1D. Figures 1A through 1D each represent a different stage in the process of creating a channel 18 in the myocardium 10, which has an outer wall (epicardium) 12 and an inner wall (endocardium) 14.

Figure 1A illustrates that the apparatus of this embodiment of the present invention has a cutting tip assembly 40 with an inner cylindrical needle 20, which has a tubular hollow internal bore 22 within its body 24. Because inner needle 20 is cylindrical, it has a lateral axis 28. Inner needle 20 has a sharpened edge 26, which may be made sharp through use of a variety of geometries (e.g., beveled inward, beveled outward). A presently preferred cutting edge defines an angle less than 45 degrees, and preferably less than 30 degrees, from the lateral axis 28. The cutting edge is sharpened using conventional techniques used in, for instance, the production of razor blades. Use of a newly sharpened cutting edge for each channel is recommended to reduce drilling trauma, tissue wrapping forces, and create cleanly excised channels.

As shown in Fig. 1E, the inner needle 20 also may have a sharpened retractable piercing tool 42 with a sharp point 44 for making a small, initial incision through the epicardium, as better described below. The piercing tool 42 moves upwardly and downwardly as shown by the directional arrow in Fig. 1E with such movement being controlled conventionally using manual or automatic control methods and apparatus.

Figures 1A-1E further illustrate that the cutting tip assembly 40 has an outer cylindrical needle 30, which has a tubular hollow internal bore 32 within its body 34. Again, because outer needle 30 is cylindrical, it has a lateral axis 38. Outer needle 30 has a sharpened edge 36, which also is made sharp through use of a variety of geometries (e.g., beveled inward, beveled outward) using the sharpening techniques discussed above, and may define an angled cutting edge as described in connection with inner needle 20.

Outer needle 30 is disposed relative to inner needle 20 roughly surrounding inner needle 20 (which may also be viewed as inner needle 20 being disposed within the internal bore 32 of outer needle 30). The lateral axis 28 of inner needle 20 and lateral axis 38 of outer needle 30 need to be substantially coincident; such an arrange-

ment of needles should allow relative lateral translation between inner needle 20 and outer needle 30, as well as differential rotation of the two needles, as shall be described below.

Alternative aspects of the inner needle are shown in Figs. 3A and 3B. In Fig. 3A, the inner needle is formed as a sharped, spiraled drill 200 which may be rotated downwardly with the outer needle 134. The drill needle configuration 200 defines a sharpened piercing tip 440 serving the same purpose as point 44 in Fig. 1E and further functions to pull excised tissue upwardly into the hollow outer needle 30. The drill needle 200 may or may not be rotated at the same speed and same time as the outer needle 30. In Fig. 3B, the inner needle 200' is formed as a screw mechanism 200' which may be rotated to advance into myocardial tissue 10. The screw mechanism 200' may be held stationary within the myocardium 10 as the outer needle 30 is rotated and moved downward to cut a channel through the myocardium 10 and, preferably, through the endocardium 14. the screw mechanism 200' also includes a pointed piercing tip 440'. Removal of the screw mechanism 200' (or the drill needle 200) and the outer needle 30 causes removal of the excised myocardial tissue which is held by the screw or drill mechanism 200, 200' within the hollow outer needle 30. Fig. 3C illustrates an additional aspect of an inner needle 200* which defines a side cut aperture 50 for holding excised tissue and a sharpened piercing tip 440*.

Any of the inner and outer needle arrangements shown in Figs. 1A - 1E and 3A - 3D enable initial piercing of the epicardium utilizing the point 44 in conjunction with Figs. 1A-1E or the piercing tips (440, 440', 440*) of the inner needle in conjunction with Figs. 3A-3C to create a small hole for entry into the myocardium. Alternatively, the smaller bore inner needle 20 may be used to create the initial opening. The creation of a small entry point is preferred to decrease bleeding at the epicardial surface and reduce any tendency for the formation of adhesions between the epicardium and the pericardial sac. The inner needle (20, 200, 200', or 200*) is advanced into the myocardium and stabilizes the entire cutting tip assembly by embedding the inner needle into myocardium. The embedded inner needle serves as an anchor to secure the assembly to the beating heart while the outer needle is rotated and advanced. The inner needles described above also hold the excised tissue in place, prior to retracting that tissue, and ensure that excised tissue is evenly distributed within the internal bore of the outer needle as the outer needle is advanced and retracted.

Another preferred embodiment of the present invention having a cutting tip assembly 400 with a single needle 402 is illustrated in Figures 2A through 2D. Again, Figures 2A through 2D each represent a different stage in the process of creating a channel 18 in the myocardium, or heart wall 10, which has an outer wall 12 and an inner wall 14.

A support means 100 with a tubular hollow internal bore 102 within its body 104 is placed against outer heart wall 12. The support means 100 may be a generally disk shaped block with a frictional contact surface, preferably with vacuum apparatus 106 to assist in removal of excised tissue and to provide a counter force to the cutting tip assembly 400. Because the internal bore 102 of the support means is cylindrical, it has a lateral axis 108. Alternatively, the support means may be a wall surrounding an aperture for inserting the cutting tip assembly into a hand piece, to be described below.

The tapered needle single needle 402 has a hollow internal bore 404 within its body 406. Again, because tapered needle 402 is cylindrical, it has a lateral axis 408. Tapered needle 402 has an edge 406, which may be made sharpened and angled as described in connection with the Fig. 1A - 1D and 3A - 3D embodiments above.

Tapered needle 402 is disposed relative to support means 100 by being disposed within the internal bore 102 of support means 100. The lateral axis 108 of internal bore 102 and lateral axis 408 of tapered needle 400 need to be substantially coincident; such an arrangement of needles should allow relative lateral translation between tapered needle 402 and internal bore 102, as well as rotation of tapered needle 402. A piercing tool, such as tool 42 shown in Figs. 1A - 1E also may be used within the bore of tapered needle 402.

In order for the various cutting tip assemblies described above to function as described herein, each cutting tip assembly preferably is linked to a hand held device, such as the hand pieces 85 and 850 shown in Figs. 5 and 6. Hand pieces 85, 850 allow automatic advancement and rotation of the cutting tip assembly.

Fig. 4 illustrates an example of linkages 70, 71 which may be used to connect the cutting tip assemblies to the hand pieces. Dual linkages 70, 71 separately mount an inner needle 20 and an outer needle 30 to allow independent rotation and movement of the inner and outer needles. The inside diameter of linkage 71 is larger than the inside diameter of linkage 70 to facilitate loading the linkages into the hand piece and to allow reciprocation of inner needle 20 within outer needle 30. Because inner needle 20 is disposed within outer needle 30, its linkage 71 may be disposed within the linkage 70 for outer needle 30. Preferably, the linkages 70, 71 fit into mating cavities in the hand pieces, although other conventional mounting arrangements may be used. The linkages 70, 71 may snap mount within the mating cavities of the hand pieces to enable new, unused cutting tip assemblies to be quickly and easily connected to the hand pieces. Such drives and their linkages must be capable of providing independent rotational and translation motion for both needles of cutting tip assembly 40. Hence, four separate degrees of freedom, two rotational and two translational, must be provided for cutting tip assemblies having an inner and outer needle. Only one

linkage need be provided for the single needle embodiment of Fig. 2. In this Fig. 2 embodiment, the drive and its linkage must be capable of providing independent rotational and translation motion for the tapered needle 402. Hence, two separate degrees of freedom, one rotational and one translational, must be provided for tip 400 of this preferred embodiment.

Referring now to Figs. 5 and 6 showing the hand pieces 85 and 850, the linkages 70, 71 for the two needle cutting tip assemblies are independently connected to, respectively, reciprocation mechanisms 74, 75 and motor drives 76, 77 to provide both axial movement and rotation. The motor drives 76, 77 may be gear motors operatively connected to a controller (not shown). The controller is activated when the operator pushes actuator 78, such as one or more triggers or buttons, to activate the motor drives 76, 77. The motor drives 76, 77 may be powered by a battery (not shown) and the controller operates to regulate the motor drives to correctly sequence channel creation. Rotating output shafts 79 of the motors 76, 77 engage gear mechanisms 81 which rotate and engage the inner and outer needles 20, 30 and cause rotation thereof.

At the same time as rotation is occurring as described above, lead screws 83 rotate in response to operation of reciprocation mechanisms 74, 75 thereby causing linear movement of piston 91. As piston 91 moves linearly towards linkage 70, inner needle 20 advances in an axial direction because it is operatively connected to reciprocation mechanisms 74, 75 by a bracket 89. Further advancement of the piston 91 causes the outer needle 30 to advance in an axial direction when the piston 91 engages linkage 71. The stroke length of the piston is controlled using mechanical or electrical stops on the lead screws. Alternatively, stepper motors may be used to advance and retract the needles thereby allowing control of the stroke of the piston.

Referring now to Fig. 5, multiple cutting tip assemblies 40 are disposed within a cartridge 80 which is removably mounted to the hand piece 85. The cartridge 80 preferable is generally cylindrical and defines a plurality of apertures for insertion of the cutting tip assemblies 40. Fig. 5 shows the cutting tip assemblies 40 in a linear arrangement for the purpose of illustration only. An advancement mechanism 82 includes a motor drive 84 which, upon activation of the actuator 78, causes rotation of the cartridge 80 to introduce a new cutting tip assembly 40 into aperture 87. As the new cutting tip assembly 40 is rotated into position, the gear motors 76, 77 cause reciprocation and rotation of the cutting tip assembly 40 as described above. Following creation of each channel and movement of the hand piece to a different location on the heart, the trigger is again pressed to reactive the sequence. Any conventional rotational mechanism may be used to rotate the cartridge 80.

Fig. 6 is a hand piece 850 for snap mount attachment of a single cutting tip assembly which may be easily disconnected prior to snap mounting a new tip into

place. The Fig. 6 embodiment operates the cutting device in the same manner as described in connection with the Fig. 5 embodiment.

The method of the present invention using a hand piece 85 or 850 with a cutting tip assembly having an inner and outer needle may now be understood. Figure 1E illustrates that, when activated, piercing tool 42 moves downwardly below the edge of inner needle 20 to create an initial hole through the epicardium prior to retraction upwardly within inner needle 20. Figure 1A illustrates that, when actuated by trigger 78, inner needle 20 is rotated about its lateral axis 28. Lateral axis 28 of inner needle 20 is held substantially perpendicular to the exterior surface 12 of the heart. Movement of the piston 91 causes the inner needle to be translated laterally along lateral axis 28 until sharpened edge 26 of inner needle 20 enters the epicardium 12 through the initial hole and travels partway into the myocardium 10. In this way a core 16 of tissue from the myocardium 10 extends into the tubular hollow internal bore 22 of inner needle 20.

Figures 1B and 1C illustrate the next step in this method. Inner needle 20 is stabilized in location by ceasing rotation of inner needle 20 and holding inner needle 20 stationary as piston 91 reaches its maximum stroke for inner needle 20. This stabilization may be improved by use of a vacuum applied to tubular hollow internal bore 22 to provide suction upon core 16 to hold it in place during further cutting. As shown in Fig. 6, the piston 91 may be hollow for attachment of a vacuum line 93 communicating with the hollow internal bores of, at least, the inner needle.

Next, outer needle 30 is actuated to rotate about its lateral axis 38 and is translated laterally along lateral axis 38, with sharpened edge 36 entering the hole through the epicardium 12 and passing into the myocardium 10 when the piston 91 engages outer needle linkage 71. This translation is continued until outer needle 30 cuts the desired depth of channel into the myocardium 10. In this manner the remainder of the heart tissue to be excised is located within hollow internal bore 32 of outer needle 30. Ideally, this will be a channel that extends completely through the endothelium 14, thus creating a channel extending into the ventricle.

Finally, Figure 1D illustrates that cutting tip assembly 40, including both inner needle 20 and outer needle 30, is removed from the myocardium 10 after lateral withdrawal of both needles, creating a channel 18. Core 16 of heart wall 10 is also removed cleanly if channel 18 extends completely through the endothelium 15.

By providing multiple degrees of freedom of motion to the cutting tip assemblies, the inner needle may be rotated for several turns in a first direction while the advancing outer needle rotates in the opposite direction. Rotation of the inner needle 20 counter clockwise to the direction of rotation of the outer needle 30 compresses the excised tissue and holds it away from the outer needle 30. The excised tissue attached to the inner needle

is twisted by the counter rotation thereby reducing its diameter to enhance channel formation and free the excised tissue from the interior wall of outer cutting needle 30. Additionally, counter rotation with the application of counter cutting forces by an applied vacuum is particularly useful to achieve a clean cut through the endothelium without leaving a flap or ragged edge.

The method of the present invention using the Fig. 2 preferred embodiment may now be understood. Figure 2A illustrates that support means 100, or distal tip of a hand piece 85 or 850, is placed adjacent to the exterior surface 12 of heart wall 10, with internal bore 102 substantially perpendicular to that surface. Tapered needle 402 is disposed within internal bore 102, or within the bore of the hand piece. Figures 1B and 1(c) illustrate the next step in this method. Tapered needle 402 is rotated about its lateral axis 408. Then, tapered needle 402 is translated laterally along lateral axis 108, with sharpened edge 406 cutting through heart wall 10, creating a core 16 of heart wall 10 contained within internal bore 404 of tapered needle 402.

This translation is continued until tapered needle 402 cuts the desired depth of channel into heart wall 10. In this manner the remainder of the heart tissue to be excised is located within hollow internal bore 404 of tapered needle 402. Ideally, this will be a channel that extends completely through the inner heart wall 14, thus creating a channel extending through heart wall 10.

Finally, Figure 2D illustrates that tapered needle 402 is laterally removed from heart wall 10, creating a channel 18. Core 16 of heart wall 10 is also removed cleanly if channel 18 extends completely through inner heart wall 115, particularly if a vacuum is applied. The tapered configuration of the needle 402 holds the excised tissue and prevents it from exiting through the narrower distal tip when the needle 402 is withdrawn.

The creation of viable channels using any of the cutting tip assemblies, with or without the hand pieces discussed above, is greatly facilitated by first heating the cutting tip assemblies to a temperature of at least 60 degrees Celsius. This provides thermal damage to the heart wall 10, in addition to the thermal damage created from frictional engagement of the cutting tip assembly, which has been found to be efficacious in production of viable channels, and simulates the thermal shock of the prior art laser methods. The cartridge embodiment of Fig. 5 may include a separate heating element(not shown), such as a conventional thermal band(not shown)to ensure that each cutting tip assembly is heated as it is rotated into place. Alternatively, a plurality of cartridges 80 may be heated in an oven (not shown) and attached with a snap lock or quick disconnect mechanism to the hand piece. Heated cutting tip assemblies for the Fig. 6 embodiment may be accomplished using a heating block 120 as shown in Fig. 7. The heating block 120 holds a plurality of cutting tip assemblies which snap mount into the hand piece 850. The aperture in the hand piece may be slipped over the linkage at the

top of the cutting tip assembly within the heating block and snapped into place without handling the cutting tip assembly.

As will be understood by those familiar with the art,

5 the present invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The scope of the present invention is therefore limited only by the scope of the claims appended hereto.

10

Claims

- 15 1. An apparatus for creating channels in tissue appropriate for improving blood flow and tissue regeneration, the apparatus comprising:
20 a generally cylindrical cutting assembly defining an axis;
tissue storage means within the cutting assembly for holding a core of tissue during and following mechanical cutting of tissue by the cutting assembly; and
means for advancing the cutting assembly into the tissue.
25
2. The apparatus of Claim 1 wherein the cutting assembly comprises at least one needle having a hollow internal bore and a distal tip, the distal tip defining a sharpened edge disposed at a specified angle to the axis and surrounding the hollow internal bore.
30
3. The apparatus of Claim 2 wherein the means for advancing the cutting assembly comprises a handpiece for attachment of the cutting assembly thereto, the handpiece having a rotation mechanism for rotating the cutting assembly and a translation mechanism for moving the cutting assembly axially.
35
4. The apparatus of Claim 3 further comprising attachment means for removably connecting the cutting means to the handpiece.
40
5. The apparatus of Claim 4 wherein the handpiece is powered for operating at least the rotation mechanism and the attachment means is at least one linkage connected to the cutting assembly and releasably mounting to the handpiece.
45
6. The apparatus of Claim 5 wherein the handpiece comprises a housing for enclosing at least one motor having at least one output shaft; gear means attached to the at least one output shaft and operatively associated with the linkage, the gear means advancing and rotating the at least one needle axially into the tissue; controller means connected to the at least one motor for processing a preselected sequence of advancement and rotation of the at
50

least one needle; and at least one actuator means for activating the motor.

7. The apparatus of Claim 1 further comprising means for heating the cutting assembly. 5
8. The apparatus of Claim 4 comprising an inner needle disposed within a hollow outer needle, the inner and outer needles each defining a substantially co-incident lateral axis to allow relative lateral translation between the inner needle and the outer needle, the attachment means enabling independent rotation and axial movement of the inner needle with respect to the outer needle. 10
9. The apparatus of Claim 8 wherein the inner needle defines a hollow internal bore and a distal tip defining a sharpened edge disposed at a specified angle to the axis and surrounding the hollow internal bore. 15
10. The apparatus of Claim 8 wherein the inner needle is shaped to define a drill tip configuration. 20
11. The apparatus of Claim 8 wherein the inner needle is shaped to define a screw tip configuration. 25
12. The apparatus of Claim 8 wherein the inner needle is hollow and defines a cylindrical outer wall, the tissue storage means is a cut away portion in the outer wall of the inner needle, and the inner needle defines a piercing tip at a distal end thereof. 30
13. The apparatus of Claim 8 wherein the means for rotating includes rotation of the inner needle counter to the outer needle. 35
14. The apparatus of Claim 5 wherein the hand piece further comprises vacuum means for applying a counterforce to cutting forces of the cutting assembly. 40
15. The apparatus of Claim 2 wherein the storage means is the hollow internal bore of the at least one needle. 45
16. The apparatus of Claim 4 for creating channels in cardiac muscle appropriate for transmyocardial revascularization, the apparatus further comprising a removable magazine attached to the handpiece, the magazine holding a plurality of cutting assemblies for automatically and rapidly rotating an unused cutting assembly into position within the handpiece to create each channel. 50
17. The apparatus of Claim 16 wherein the cutting assembly further comprises a piercing tool for creating a small entry hole through epicardium to allow introduction of the at least one needle into myocardium. 55

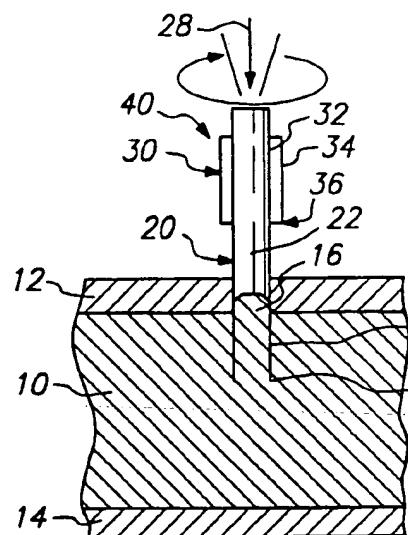


FIG. 1A

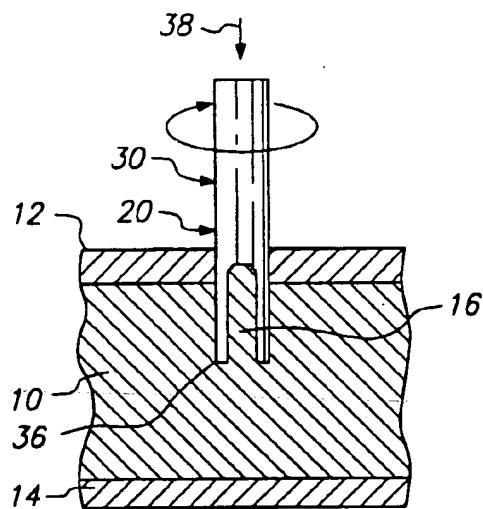


FIG. 1B

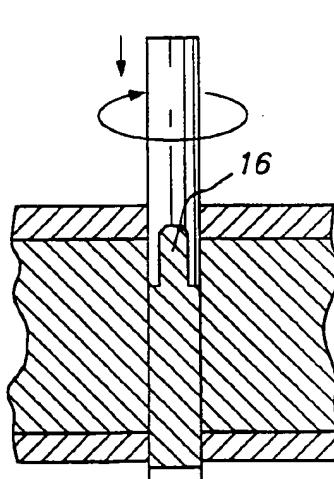


FIG. 1C

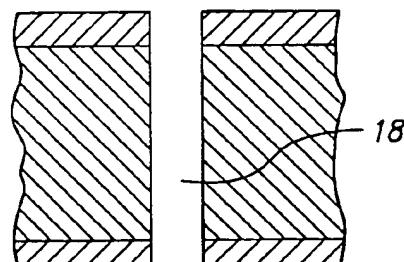


FIG. 1D

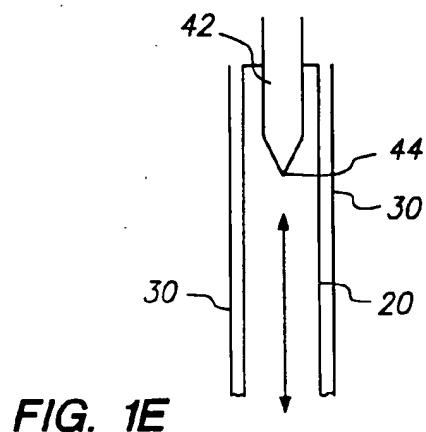
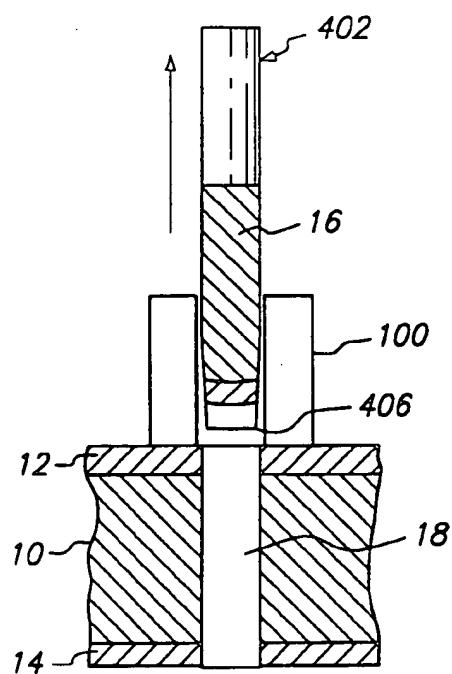
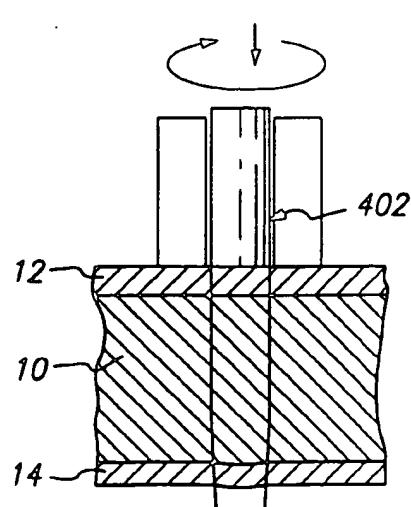
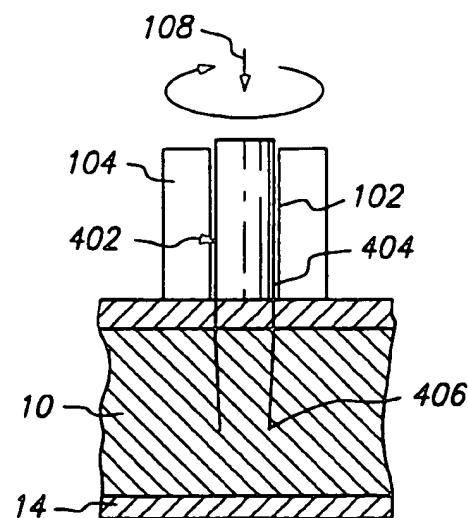
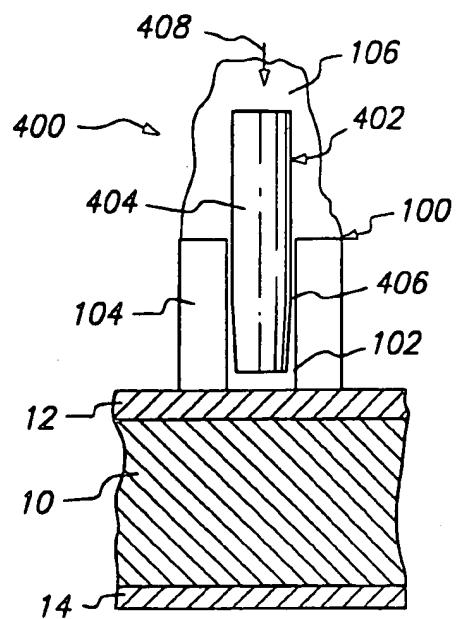


FIG. 1E



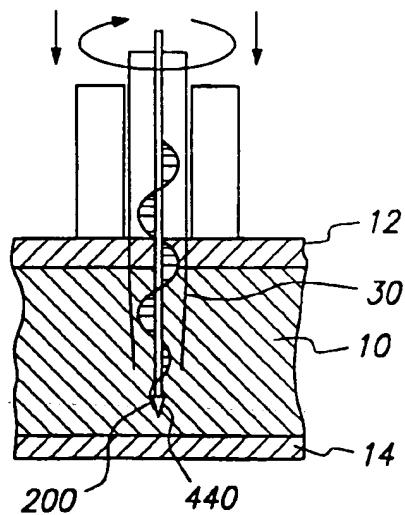


FIG. 3A

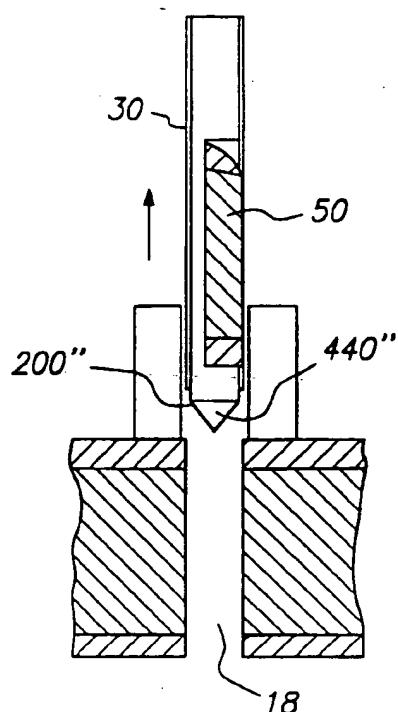


FIG. 3C

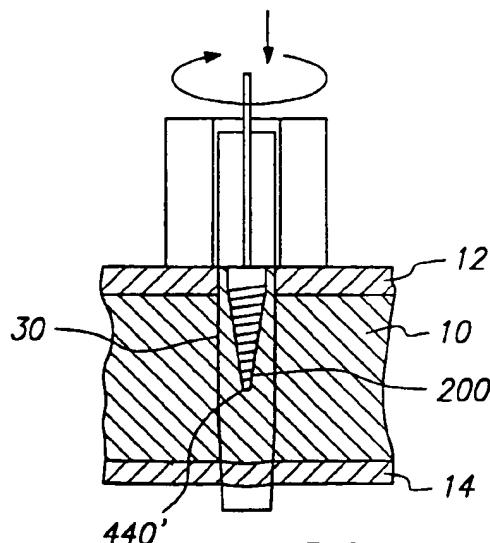


FIG. 3B

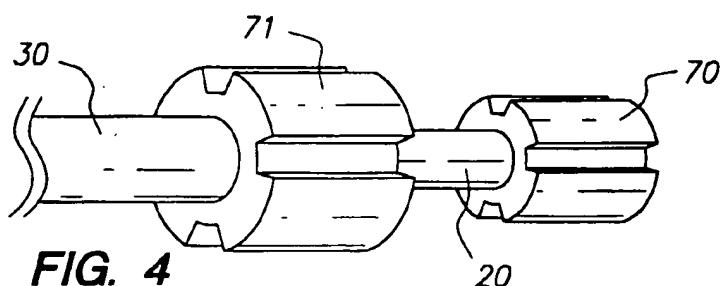


FIG. 4

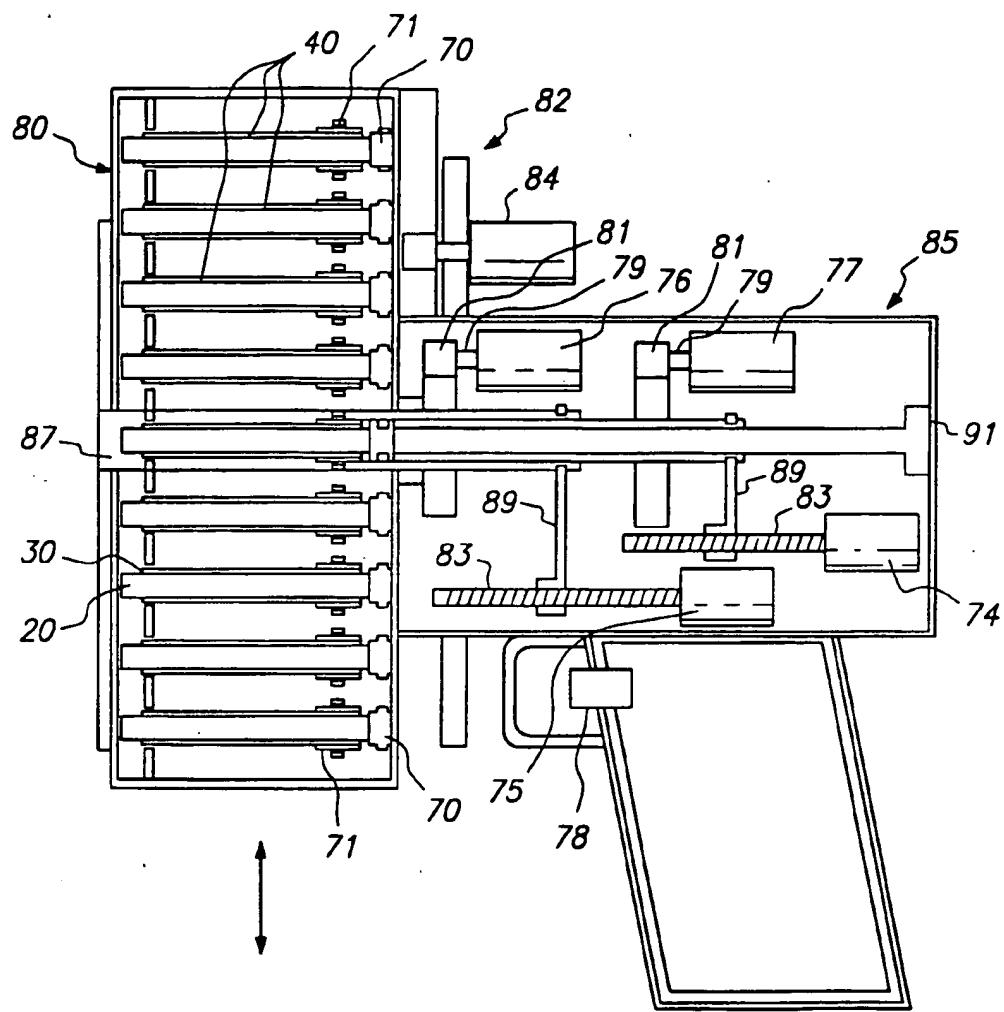


FIG. 5

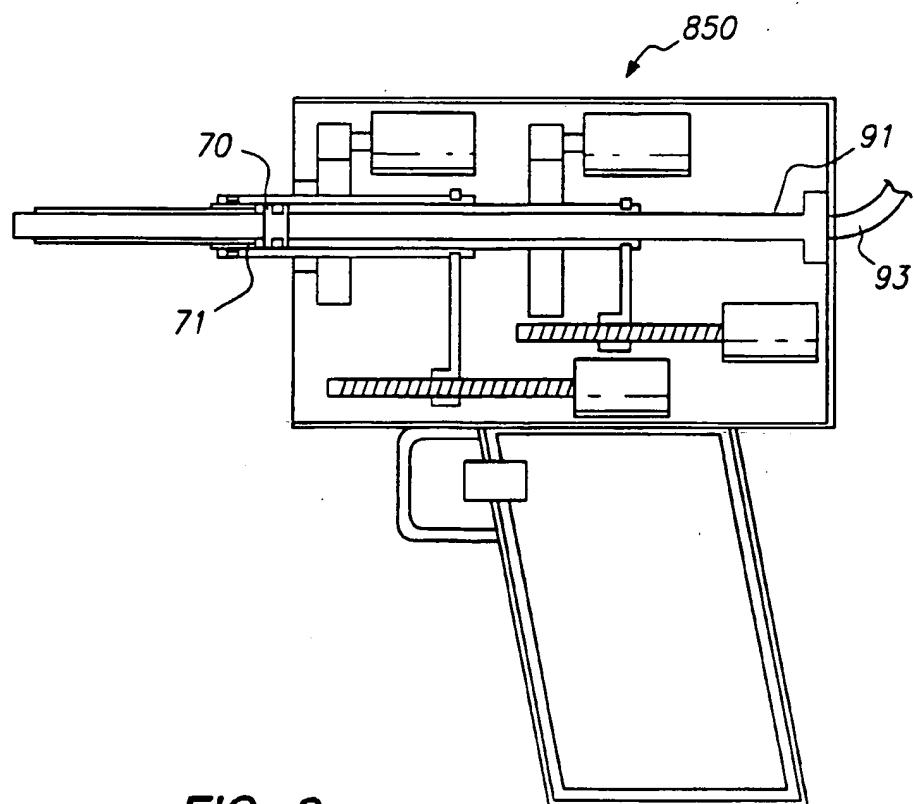


FIG. 6

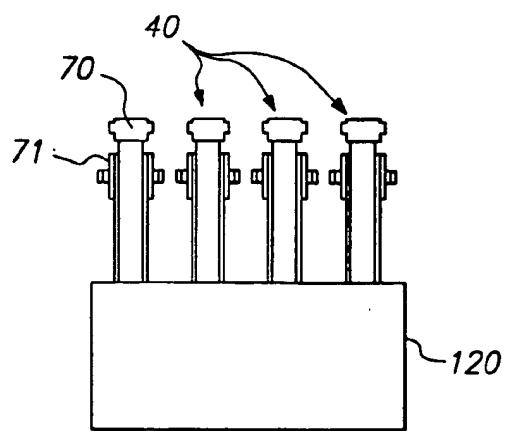


FIG. 7



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number

EP 97 30 6377

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	US 3 913 566 A (LACEY ROBERT L)	1-4,15	A61B17/32
A	* the whole document *	18	

A	EP C 515 867 A (UNIV COLUMBIA)	1	
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D,A	US 5 380 316 A (AITA MICHAEL ET AL)	1	
	* the whole document *		

The present search report has been drawn up for all claims			
Place of search	Date of completion of the search	Examiner	
THE HAGUE	27 November 1997	Verelst, P	
CATEGORY OF CITED DOCUMENTS			
X , particularly relevant if taken alone	1. prior art or principle underlying the invention		
✓ , namely relevant if combined with another document of the same category	2. earlier patent document, but published on, or after the filing date		
A , technological background	3. document cited in the application not directly cited for other reasons		
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P , intermediate document	5. member of the same patent family, corresponding document		

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